antipsychotics, lack of efficacy or tolerability and poor compliance remain frequent reasons for change of therapy.

PMH59

THE ELECTRONIC SCHIZOPHRENIA TREATMENT ADHERENCE REGISTRY—E-STAR: BASELINE RESULTS FOR GERMANY, SPAIN AND AUSTRALIA

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OBJECTIVES: E-STAR is an ongoing, international, observational survey evaluating long-term clinical and economic outcomes in patients switched to a new antipsychotic. **METHODS:** Data are collected via a secured web-based system, retrospectively for 12-months and prospectively for two-years. Patient demographics, treatment and hospitalisation history, reason for initiating new treatment, Clinical Global Impression—Severity (CGI-S), Global Assessment of Functioning (GAF) and adverse event data are collected. **RESULTS:** Complete baseline and retrospective data are currently available for 1920 patients enrolled: Germany (n = 744), Spain (n = 709), Australia (n = 467). Patients reported here switched to long acting injectable (LAI) risperidone Mean age was 39.5 years (SD 11.8; range 37.5–41); majority were male (mean 61%; range 56–70%). 98% had a diagnosis of schizophrenia or schizoaffective disorder (range 98–100%). Mean duration of illness was 10.8 years (SD 9.3; range 9.2–12.6 years). Majority of patients (>80%) at baseline had a CGI-S score of 4–6 indicating that patients were moderately (35%), markedly (34%) or severely (18%) ill. The GAF scores were similar across countries (mean 46; SD 15; range 43–48). There were country differences in hospitalisation history during the 12-month retrospective period: 28%, 70%, and 17% of patients in Germany, Spain and Australia respectively had no hospitalisations; for patients with hospitalisations, the mean number of days hospitalised per patient was 58.2 (SD 53.1), 38.3 (SD 51.1), and 66.9 (SD 90.3) respectively. Prior to the switch to (LAI) risperidone, 67–90% patients were taking oral atypicals, 27–35% oral conventionals, and 22–52% depot conventionals. The most frequent reason for switching was compliance: Germany (37%), Australia (52%), Spain (30%). **CONCLUSIONS:** Compliance remains an important treatment issue even for those treated with atypicals. Continued enrollment, and follow-up will enable a better understanding of a broader range of treatment patterns in schizophrenic patients

PMH60

THE ELECTRONIC SCHIZOPHRENIA TREATMENT ADHERENCE REGISTRY—E-STAR: DATA QUALITY ASSURANCE GATE KEEPING METHODS

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OBJECTIVES: E-STAR is an international, non-interventional, observational study of clinical and economic outcomes in schizophrenia/schizoaffective patients who switch to a new antipsychotic. **METHODS:** Data over a 12-month retrospective and 24 month prospective period from in- or out-patients who start on a new antipsychotic medication are collected via a secure, privacy-protected web-site. All data are automatically checked against validation rules at the point of entering the study. The validation rules are established in consultation with specialists in data analysis and key opinion leaders, and are designed to prevent missing data, duplicate data and data outside pre-established, reasonable ranges. These require confirmation by the physician before the system will accept them. If data is entered incorrectly, the physician submits correction requests via an audited online data change request system. A further supplemental audit process is used to control quality of uploaded data. This process uses monthly reports to identify potential inconsistencies within the dataset after data has been validated at entry. **RESULTS:** Uploaded data undergoing quality control checks, requiring adjustment by physicians, is minimal. Audit reports have helped redress data entry training issues, further enhancing data accuracy. Analysis is only conducted on patients after resolution of outstanding supplemental data queries. **Conclusion:** This largely automated three stage quality control process is important to the implementation of non-interventional, observational research such as this, where the goal is to study outcomes in a generalisable, representative patient cohort. This permits the inclusion of patients from a broad geographic region, which will add significantly to our understanding of the use of anti-psychotics in actual clinical practice, outside of the influence of clinical trial settings. This also allows for much faster analysis and presentation of robust, pragmatic outcomes data.

PMH61

COMPARISON OF OUTCOMES REPORTED BY INDIVIDUALS WITH SCHIZOPHRENIA RESIDING IN THE COMMUNITY AND OBJECTIVE OUTCOMES REPORTED BY CAREGIVERS

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OBJECTIVES: Compare patient- and caregiver-reported outcomes on 25 objective questions contained within the 51-item Schizophrenia Outcomes Assessment Project (SOAP) quality of life survey. **METHODS:** In total, 1500 community-residing individuals with schizophrenia in five states (Massachusetts, South Carolina, Wisconsin, Arizona, Washington) completed SOAP-51 survey at baseline and weeks four, five, and 12. Previously, factor analysis indicated that SOAP-51 had eight factors (satisfaction, self concept, work/role, mental health, interpersonal, medication effects, activities of daily living, and physical function) with Cronbach alphas ranging from 0.728–0.937 and test/retest intraclass correlations >0.70 for all but one factor. An expert panel identified 25 SOAP items that could be objectively measured. This 25-item subset was given to each patient's primary caregiver concurrent with each patient's SOAP-51 administration. Caregivers were asked to answer each item in two ways: 1) What is your objective response?; and 2) What do you think is the patient's response? Three correlation sets were performed for week-four responses: a) caregiver's objective responses compared to caregiver's estimation of patient's responses (Correlation A); b) caregiver's objective response compared to patient's responses (Correlation B); and c) caregiver's estimation of patient's responses compared to patient's responses (Correlation C). **RESULTS:** Strongest correlations occurred in Correlation A [factor scores for caregiver's objective responses compared to caregiver's estimation of patient's responses (0.534–0.862)]; lowest for Correlation B [caregiver's objective response compared to patient's responses (–0.292–0.367)]; and intermediate for Correlation C [caregiver's estimation of patient's responses compared to patient's responses (–0.353–0.564)]. Physical function factor correlations were the strongest in Correlation A (0.862), but the lowest in Correlation B (–0.292) and C (–0.353). **CONCLUSIONS:** Caregiver objective assessments of individuals with schizophrenia can vary markedly from patient-reported outcomes, but asking caregivers to view the world through the eyes of the patient closes this gap. Asking caregivers

to assume a patient's perspective may improve patient-caregiver communications.

PMH62

VALUATION OF SCHIZOPHRENIA-RELATED HEALTH STATES BY THE GENERAL POPULATION USING THE AQOL, TIME TRADE-OFF AND VISUAL ANALOGUE SCALES

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OBJECTIVE: To assess differences in the valuation of eight schizophrenia-related health states using a multi-attribute utility instrument (MAU)—the Assessment of Quality of Life Questionnaire (AQoL), and two scaling techniques: the time trade-off (TTO) and a visual analogue scale (VAS). **METHODS:** Eight schizophrenia-related health state scenarios based on severity of symptoms were presented to 87 participants from the general population. Scenarios were: A) "good" function with no movement disorders [extrapyramidal symptoms]; B) "good" function with movement disorders; C) "poor" function with no movement disorders; D) "poor" function with movement disorders; E) hospitalised relapse with no movement disorders; F) hospitalised relapse with movement disorders; G) post-hospitalisation with no movement disorders; and H) post-hospitalisation with movement disorders. Participants were educated about how the symptoms described in these scenarios could impact on quality of life and were then asked to value each health state using the AQoL, TTO, and a VAS ranging from 0–100. **RESULTS:** Mean utility values for all health states ranged from 0.68 to 0.01, 0.80 to 0.53, and 0.74 to 0.17 for the AQoL, TTO and VAS, respectively. For each instrument or scale there was a trend for higher utility values to be associated with better outcomes and lower utility values to be associated with poorer outcomes. There were differences between the global results for AQoL, TTO and VAS [Kruskal-Wallis test ($p < 0.001$)] and differences between the utility measures for each health state, except between TTO and VAS results for health state A ($p = 0.655$), and between the AQoL and VAS results for health state G ($p = 0.094$). **CONCLUSION:** Utility values varied across health states and in most cases differed significantly between instrument and/or scale. For schizophrenia, the results from AQoL are most sensitive to differing symptom severity. However, further research comparing the different utility instruments is required in this disease area.

PMH63

GREATER DEPRESSIVE SYMPTOMS ARE ASSOCIATED WITH WORSE FUNCTIONAL OUTCOMES IN PATIENTS DIAGNOSED WITH SCHIZOPHRENIA OR SCHIZOAFFECTIVE DISORDER

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OBJECTIVE: To assess the relationships between depressive symptoms and functional outcomes in the treatment of patients diagnosed with schizophrenia or schizoaffective disorder. **METHODS:** This was a post-hoc analysis of a randomized, double-blind, 24-week study of antipsychotic treatment for patients diagnosed with schizophrenia or schizoaffective disorders with prominent depressive symptoms ($N = 394$). Measures included the SCAP Health Questionnaire (SCAP-HQ) for functional outcomes and the Montgomery-Åsberg Depression Rating Scale (MADRS) for depressive symptoms. Associations between depressive symptoms at baseline and functional outcomes at baseline and at 24-weeks (LOCF) were evaluated controlling for severity of schizophrenia symptoms (measured with the Positive and Negative Symptoms Scale (PANSS)) and extrapyramidal symptoms measured with the Barnes Akathisia Scale, the Simpson-Angus Scales, and the Abnormal Involuntary Movement Scale (AIMS). **RESULTS:** At baseline, depressive symptoms were significantly correlated with baseline PANSS Positive Symptoms and General Psychopathology ($p < 0.001$), but not with Negative Symptoms. At baseline, greater severity of depressive symptoms significantly correlated with a higher likelihood of baseline violent behaviors, suicidal ideations, suicide attempts, and substance use; and a decreased likelihood of baseline participation in a day treatment program and common leisure activities (all $p < 0.050$). Baseline severity of depressive symptoms was significantly associated with poorer mental health functioning, increased likelihood of suicidal ideations and substance use, and with decreased likelihood of participation in a day treatment program at endpoint (all $p < 0.050$). **CONCLUSIONS:** Depressive symptoms in schizophrenia or schizoaffective disorder are associated with worse functional outcomes, both concurrently and after 24-weeks of treatment with antipsychotic medications.

PMH64

USE OF THE CAREGIVER STRAIN QUESTIONNAIRE IN AN INTERNATIONAL STUDY

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OBJECTIVES: Prior to use in an international study involving children and adolescents suffering from schizophrenia or bipolar disorders, the original 21-item Caregiver Strain Questionnaire (CGSQ) underwent linguistic validation in 19 languages. The original scale, which measures the strain of caring for children with emotional and/or behavioural problems on their caregivers, was developed in US English. A rigorous methodology was required to ensure conceptual equivalence and cultural relevance across different languages. **METHODS:** The translation process was conducted by a specialist in each target country using the following standardized methodology: 1) two forward translations by professional translators who were native speakers of the target language and fluent in English; 2) comparison and reconciliation of the translations by the specialist in the target country and the translators; 3) backward translation by a native English speaker; 4) comparison of source and backward version; 5) review by a clinician; and 6) comprehension test on five parents of children suffering from schizophrenia or bipolar disorders. **RESULTS:** The translation process revealed two types of challenges: a) the translation of technical terms and b) the translation of idiomatic expressions. In the first case the expression "negative mental and physical health effects" required a simplified description in the translations. Similarly, the term "caregiver", having no literal equivalent, had to be replaced by the mention of the actual person providing care. As for translations of idiomatic expressions, paraphrases were often needed to convey the intended meaning. **CONCLUSIONS:** The 19 language versions of the CGSQ were established according to a rigorous translation methodology. The process aims to ensure conceptual equivalence across different language versions to facilitate international comparison and pooling of data. The linguistic validation process as a whole supports the advantage of integrating international feedback on concepts and wording before a questionnaire is finalized.